

State of Wisconsin Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE:

September 3, 2014

TO:

Board of Agriculture, Trade and Consumer Protection

FROM:

Ben Brancel, Secretary A

Steve Ingham, Division of Food Safety Administrator West Ingham

SUBJECT:

ATCP 88, 75, and 71-Regulation of Egg Grading, Handling,

Packaging, Labeling, and Retail Sales and Affecting Small

Business; Final Draft

PRESENTED BY: Steve Ingham

REQUESTED ACTION:

At the September 17, 2014 Board meeting, the department will ask the DATCP Board to approve a final draft rule (copy attached) related to grading and labeling, handling, packaging, and retail sales of eggs. Current regulations related to shell eggs are found in several administrative rules and the proposed rule changes affect ATCP 88, Egg Grading, Handling and Labeling; ATCP 70, Food Processing Plants; and ATCP 75, Retail Food Establishments.

SUMMARY:

Background

The Division of Food Safety (DFS) has received numerous inquiries requesting clarification of the licensing and inspection requirements for shell eggs, particularly from people who seek to sell eggs at their farm or at farmers' markets. This rule is a comprehensive revision of food safety regulations related to eggs. If adopted, the rule will assist those people who seek to sell a small number of shell eggs, as well as those who operate larger egg production businesses, by clarifying licensing and inspection requirements. The rule was also developed in response to a request from the legislature. The Assembly Committee on Consumer Protection reviewed ATCP 88, Egg Grading, Handling and Labeling as part of the legislature's "Right the Rules" initiative. The committee identified inconsistencies and potential improvements to the rule and sent a letter requesting that DATCP consider revising the rule to address those issues. Further, this rule will implement 2013 Wisconsin Act 245, which exempted egg producers with a flock of not more than 150 laying birds who sell eggs directly to consumers on the premises where the eggs were laid, at a farmers' market or on an egg sales route from obtaining a food processing license if they meet packaging and labeling requirements. The rule also exempts producers from obtaining a retail food establishment license when selling eggs to consumers at the producer's farm or as part of a community-supported agriculture business.

Rule Content

The rule repeals the existing ATCP 88, Egg Grading, Handling and Labeling and comprehensively rewrites it to clarify the regulatory requirements applicable to egg producers and egg handlers, and makes minor revisions to ATCP 70 and 75. The rule consolidates egg-related requirements in one rule, reducing the need for egg producers to consult multiple chapters of rules to understand regulatory requirements. The rule will help businesses by eliminating the requirement for small-scale egg producers to hold a food processing plant license when selling eggs at a farmers' market, on an egg sales route, or at the egg producer's farm. In addition, the rule clarifies licensing requirements for eggs sold to consumers via community-supported agriculture businesses, and eggs sold to operators of community-supported agriculture businesses. The rule also removes obsolete provisions in the existing rule, provides explanations to improve rule clarity, and spells out federal registration requirements that must also be met by some egg producers and egg handlers. Specifically, the rule addresses the following:

Food Processing Plant and Retail Establishment Rules

- The rule revises ATCP 70, Food Processing Plants, to exempt from food processing plant licensing requirements: 1) egg producers, with flocks of not more than 150 laying birds, provided they only sell eggs directly to consumers on the premises where the eggs are laid, at a farmers' market, or on an egg-sales route, and 2) egg producers registered with the department who sell nest-run eggs to a licensed egg handler.
- The rule modifies ATCP 70 to refer egg handlers licensed as food processors to specific sections of ATCP 88 that relate to construction, maintenance, sanitation, packaging and labeling requirements for egg handling.
- The rule also revises the Wisconsin Food Code, which is found in the appendix of ATCP 75, Retail Food Establishments, to clarify that eggs sold by egg handlers holding a food processing plant license issued by another state, or who are selling eggs directly to the consumer and exempted under ATCP 88.02, are allowed to sell eggs at retail. The rule also updates the cited location of restricted egg tolerances from ATCP 88.06 to ATCP 88.26.

Title and Organization

• The rule retitles ATCP 88 from "Egg Grading, Handling, and Labeling" to "Eggs," reflecting the broader scope of the rule. The rule organizes provisions into six subchapters to improve ease of use, reorganizes and renumbers existing provisions that are retained from the current rule, and creates new provisions throughout the rule.

General Provisions

ATCP 88.01-Definitions. The rule adds definitions to ATCP 88 for "ambient temperature,"
 "balut," "check," "community-supported agriculture business," "consumer," "egg handler,"

"egg producer," "egg sales route," "farmers' market," "incubator reject," "leaker," "loss," "nest-run," "official egg products plant," "restricted egg," "storage," and "U.S. Consumer Grade B." The rule also expands the definition of "egg" to include turkey, duck, goose, guinea or other avian species whose eggs are consumed by humans. The rule also creates definitions for important federal regulations related to eggs.

- ATCP 88.02-Licensing and registration. The rule creates a provision describing food processing plant, food warehouse, and retail food establishment licensing and registration requirements for egg producers and egg handlers. The rule creates a food processing plant license exemption, consistent with 2013 Wisconsin Act 245, for small-scale egg producers who sell eggs directly to consumers. The rule also establishes a food processing plant license exemption for egg producers who sell nest-run eggs to an egg handler, provided these producers register with the department. The rule clarifies that a retail food establishment license is required to sell eggs directly to consumers at farmers' markets and on egg sales routes. Consistent with existing division policy, the rule clarifies that a retail food establishment license is not required for an egg producer to sell eggs directly to consumers at the egg producer's premises or via a community-supported agriculture business operated by the egg producer.
- ATCP 88.04-Federal registrations and records. Under federal law, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) require registration for certain egg producers and handlers. The rule requires egg producers to comply with FDA or USDA requirements for registration. To ensure Wisconsin egg producers are meeting critical food safety requirements in the federal egg safety rule (21 CFR 118.11), the revised rule requires Wisconsin egg handlers, who are receiving eggs from producers who own 3,000 or more laying birds, to maintain records showing that the producers are registered with the FDA. Registration is one way to ensure that large egg producers covered by the federal egg safety rule are meeting federal regulations designed to reduce the risk of Salmonella Enteritidis (SE).

Egg Facilities

- ATCP 88.06-Egg handling and storage facilities. The rule lists requirements, consistent with those for all food processing plants, related to construction and maintenance of egg handling and storage facilities, doors and windows, lighting, toilet facilities, cleaning facilities, garbage and refuse disposal, and control of pests.
- ATCP 88.08-Egg handling rooms. The rule retains the requirement that egg storage areas maintain eggs at appropriate temperatures and be equipped with temperature measuring devices. The rule also retains the requirement that candling areas be dark enough to permit accurate determinations of egg quality. The rule adds cleanliness requirements for egg washing and egg grading rooms.

• ATCP 88.10-Operations water. The rule specifies requirements to ensure water, used in egg handling facilities, is tested and meets drinking water standards. Egg handling facilities are required to keep the results of all health-related tests conducted on operations water.

Equipment and Utensils

- ATCP 88.12-Equipment and utensil requirements. The rule presents requirements to ensure equipment and utensils used in egg handling establishments are of sanitary design and construction.
- ATCP 88.14-Cleaning and sanitizing equipment and utensils. The rule requires that all egg
 contact surfaces of equipment and utensils be cleaned and sanitized after each day's use, or
 more frequently if necessary. It outlines the procedure for obtaining department approval for
 alternative cleaning and sanitizing procedures and methods for storing equipment and utensils.

Egg Handling Operations

- ATCP 88.16-Personnel standards. The rule lists requirements for personnel, including
 cleanliness, clothing and jewelry, employee health, and prohibitions against consumption of
 food or beverages, or use of tobacco, in egg handling rooms.
- ATCP 88.18-Temperature standards. The rule identifies temperature standards for eggs before and after packing and prohibits the sale of shell eggs that have been frozen. The rule contains added temperature standards for eggs during transport and at retail sale, with the retail sale temperature standards consistent with the Wisconsin Food Code. The rule contains added temperatures standards for baluts, which are edible fertile eggs.
- cleaning and storage. It no longer cites the "List of Proprietary Substances and Nonfood Compounds," which is no longer published by USDA, as a reference for identifying acceptable egg- cleaning or -sanitizing compounds. Instead the rule requires that compounds used to clean or sanitize eggs shall be either 1) generally recognized as safe under 21 CFR parts 182 and 184, and used in accordance with good manufacturing practices under 21 CFR 182.1, 2) approved by the U.S. food and drug administration as a food additive under 21 CFR parts 172 174, and 180, and used in accordance with the conditions of this approval, or 3) approved by the U.S. food and drug administration as a sanitizer under 21 CFR 178.1010, used at concentrations specified therein, and registered for this use with the U.S. environmental protection agency. The rule contains an added provision related to the use of ultraviolet light for sanitizing the surface of shell eggs. The rule requires that dirty eggs, which cannot be cleaned, shall be discarded and that eggs shall be handled and stored in a safe, sanitary and orderly manner to protect the safety of the eggs and allow for ready inspection and movement of eggs.

- ATCP 88.22-Candling. The rule requires use of a candling light or automated grading equipment for determining the interior and exterior quality of eggs, and use of a candling light to verify the performance of automated grading equipment.
- ATCP 88.24-Grading standards for chicken eggs. The rule clarifies that grading standards apply to chicken eggs only. The rule maintains the current requirement that graded eggs sold or distributed in Wisconsin shall be labeled for grade and meet grade B or better standards under the United States grade standards, unless they are clearly labeled as "ungraded." The rule maintains the current size or weight class requirement for chicken egg sizes. The rule contains an added table illustrating weights for each size or weight class.
- ATCP 88.26-Minimum tolerance standards. The rule maintains the minimum tolerance standards for eggs of grade B quality, whether labeled as "graded" or "ungraded", unless the eggs are sold on the premises directly to a household consumer and the eggs are labeled as "ungraded."
- ATCP 88.28-Restricted eggs. The rule adds a prohibition against the sale of restricted eggs and provisions describing the disposition of restricted eggs.
- ATCP 88.30-Shell egg protection. The rule maintains the current provision that oiling eggs, to protect shells, shall be performed in a manner that prevents egg contamination and preserves egg quality. The rule removes the requirement that oil used to protect eggs must be listed in the "List of Proprietary Substances and Nonfood Compounds," which USDA no longer publishes, and substitutes a requirement that oil must comply with 21 CFR 172.878 and 178.3620(a) relating to mineral oil.

Packing and Labeling

- ATCP 88.32-Egg packing. The rule maintains current requirements related to egg packing, but revises the title of s. ATCP 82.32(1) to clarify that packing practices shall maintain egg quality. The revised rule adds provisions that eggs may be packed in used, clean cartons as long as the seller obliterates all markings that do not pertain to the eggs being sold.
- ATCP 88.34-Egg labeling. The rule maintains the current requirements related to egg labeling, except that it adds the requirement that egg cartons include a label with the statement "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly." The rule specifies the font size and location on the package of the safe handling label. The rule maintains requirements related to the packing date, expiration date, and use by date, and requirements related to egg shipping containers.
- ATCP 88.36-Labeling of baluts. The rule adds a provision establishing labeling requirements for baluts, including a label clearly indicating that baluts must be stored at a temperature of 41°F or colder.

- ATCP 88.38-Deceptive practices. The rule retains the current provisions against deceptive practices, with an added prohibition against any nutrient content or health claims that do not comply with the requirements of 21 CFR part 101.
- ATCP 88.40-Dealers buying eggs from producers; receipts. The rule maintains the provision
 related to dealers buying eggs from producers except that, for clarity, it re-organizes the
 provisions into three, rather than two provisions, and specifies that the producer keeps records
 of eggs sold to dealers.
- ATCP 88.42-Recall plan. The revised rule requires egg handlers to develop a written plan for recalling eggs in the event of a foodborne illness linked to the eggs handled at the establishment. The rule identifies the recall plan contents, and requires the egg handler to update the plan as necessary and make it available to the department for inspection and copying upon request.
- ATCP 88.44-Enforcement. The rule includes the regulatory basis for enforcing ATCP 88.

Summary of, and Comparison with, Existing or Proposed Federal Statutes and Regulations

In general, rules designed to ensure egg safety and consistent quality and marketing of eggs cover activities related to: 1) flock health and farm sanitation; 2) egg grading, sanitation, temperature control, packaging, and labeling at egg processing facilities; and 3) transportation, handling, and storage of eggs for retail sale. Federal egg regulations consist of several rules involving two agencies, each responsible for different activities designed to promote the production and sale of safe eggs, and consistent egg quality and marketing. The rule clearly differentiates Wisconsin's requirements and those of federal agencies in regulating egg packaging and sales.

Federal Egg Regulations

The Egg Products Inspection Act (Title 21 USC, Chapter 15) authorized the USDA to create regulations (7 CFR Part 57) for egg processing operations. Egg processing operations, now defined in ATCP 88 as "official egg products plants," generally produce products other than shell eggs, such as pasteurized whole eggs and dried egg whites. For eggs moving in interstate or foreign commerce, federal law and regulations pre-empt state statutes and regulations, involving temperature control, quality or grade, condition, weight or quantity. A voluntary egg grading service is administered by USDA under the authority of the Agricultural Marketing Act of 1946 as amended (Title 7 USC, Chapter 1621 et seq.; now referred to in the rule as the "federal egg grading act") and requirements, formerly found in 7 CFR part 56, but now available as guidance from USDA's Agricultural Marketing Service (AMS 56), essentially use the same egg grading standards which are maintained in ATCP 88.

Under the Federal Food, Drug and Cosmetic Act (Title 21 USC, Chapter 9), and the Public Health Service Act (Title 42 USC, Chapter 264), the US Food and Drug Administration (FDA) has enacted egg safety regulations (21 CFR 16.5 (a) (5) and 21 CFR part 118, now referred to in ATCP

88 as the "federal egg safety rule") applying to shell egg producers with 3,000 or more laying hens at a particular farm, who are not selling all of the eggs directly to consumers or are transporting eggs for processing. The regulations require these egg producers to register with FDA and to develop a written SE prevention plan for each farm.

Federal and State Regulatory Roles

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for activities related to disease control in flocks of laying hens. In addition, the Agricultural Marketing Service (AMS) is responsible for quality grading for shell eggs and the Shell Egg Surveillance program, which ensures eggs for sale meet Grade B or better standards. Finally, the Food Safety and Inspection Service (FSIS) is responsible for inspecting egg products sold in interstate commerce and re-inspecting imported egg products. The FDA, on the other hand, is responsible for ensuring sanitation and safety control measures at the farm, monitoring safe handling and good manufacturing practices in shell egg packaging plants that do not use the USDA's shell egg grading service, and for managing recalls involving shell eggs or egg products inspected by either the FDA or the USDA. State and local agencies typically are responsible for working in cooperation with the FDA to inspect shell egg packaging plants that do not use the USDA's shell egg grading service and for inspecting retail food establishments. Wisconsin currently regulates voluntary egg grading in plants that do not use the USDA's shell egg grading service, egg packaging and warehouse activities, and retail sales of eggs.

Comparison with Rules in Adjacent States

Illinois requires egg producers to hold a limited or full license, for \$15 and \$50, respectively. Illinois also assesses a per-case inspection fee on eggs sold in-state. Egg producers are not required to hold an Illinois egg license to sell nest-run eggs from the producer's flock to household consumers for the consumers' own personal use. The eggs must be sold on the premises where the flock is located. Producers who sell eggs to licensed grading stations also do not require an Illinois egg license. A limited Producer-Dealer egg license is required for producers selling graded eggs from their own flock of fewer than 3,000 birds when the eggs are sold off the premises where the flock is located. Egg producers who sell eggs from their own flock of 3,000 or more birds plus eggs from other than their own production, off the premises where their flock is located, are required to obtain a full Producer-Dealer egg license. Wholesale and retail sales of eggs must meet all requirements found in the Illinois Egg & Egg Products Act.

Iowa requires handlers of candled and graded eggs to hold a license, the cost of which is based on the number of eggs sold in a "snapshot" month. The fee ranges from \$15 for egg handlers who purchase or handle fewer than 125 cases in the month of April of a calendar year to \$250 for those who purchase or handle 10,000 cases or more during that month. Producers who sell eggs exclusively from their own flocks directly to handlers, or to consumers, are exempt from licensing.

Michigan does not require a license for selling eggs obtained from flocks of fewer than 3,000 laying hens if the sales are made directly to consumers. Any other sales, including those

transacted with consumers by internet, mail, or consignment, are only allowed if the seller holds a \$175 license.

Minnesota assesses an annual inspection fee, based on number of eggs sold, which costs from \$12.50 to \$312. A food handler license is also required for certain sales. The cost of a food handler license is based on the gross annual food sales and ranges from a fee of \$77 for establishments with gross annual food sales of less than \$50,000 to a fee of \$2,001 for establishments with gross food sales of over \$25 million. Producers may sell eggs directly from their farm to individual customers without meeting licensing, registration, or inspection requirements. Producers may also sell eggs at farmers' markets without licensing or registration, but the eggs must be candled, labeled with the producer's name and address and kept at a temperature of 45° F or colder. Producers with fewer than 3,000 hens may sell eggs to grocery stores, restaurants or other food businesses without a license if they register with the Minnesota Department of Agriculture (MDA). There is no fee for registration and no routine inspection of the producer, although MDA may inspect the premises if they receive a complaint about the producer.

Currently, Wisconsin egg handlers must hold a food processing plant license (potentially hazardous foods category) with the license fee based on annual sales and ranging from a fee of \$95 for establishments with annual sales of less than \$25,000 to a fee of \$835 for food processors with annual sales of at least \$250,000. Wisconsin currently also requires egg producers who sell eggs directly to consumers at venues other than their farms, such as at a farmers' market, to hold a retail food establishment license. The fee for a retail food establishment license issued by DATCP ranges from \$45 to \$685, depending on the scope of the establishment and its total annual sales, with small egg producers typically paying \$45. If the retail sales occur in jurisdictions where local health agents are under contract with the department to conduct retail food establishment inspections, the fees may differ. The ATCP 88 rule now contains exemptions from the food processing plant license for producers who sell eggs from small flocks, and producers who sell only nest-run eggs to egg handlers. This approach is consistent with that taken in neighboring states to minimize regulatory costs for small-scale, direct-sale egg producers.

USDA grading standards are adopted in each of our neighboring states and those standards generally require that eggs sold to retailers must be Grade B or better. Illinois, Iowa, and Minnesota require candled eggs to be stored at 45° F or colder. Michigan requires eggs to be held and transported at no more than 45° F ambient temperature beginning 36 hours after the time of laying. Illinois requires nest-run eggs to be held at 60° F or less at all times. Since temperature control is an essential means of protecting the public from egg-borne illnesses, the Wisconsin rule requires eggs handled by licensed operators to be kept at 45° F or colder before and after packing and during transport, and 41° F or colder for retail sale. Egg producers who are exempt from the requirement to hold a food processing plant license must keep the eggs at an ambient temperature of 41 degrees Fahrenheit or below for retail sale.

Illinois, Iowa, and Minnesota require record-keeping associated with graded-egg sales and retention of these records for varying lengths of time. Wisconsin's rule is consistent with neighboring states in this regard.

Public Hearing

DATCP held four public hearings:

July 15, 2014	Wausau, Wisconsin
July 18, 2014	Mauston, Wisconsin
August 4, 2014	Madison, Wisconsin
August 6, 2014	Fond du Lac, Wisconsin

Following the public hearings, the hearing record remained open until August 20, 2014 for additional written comments. Two people attended the hearings and one of the attendees also submitted written comments. A summary of the oral and written comments may be found in Appendix A.

Changes from the Hearing Draft

DATCP made the following changes from the Hearing Draft:

- Made all technical rule changes suggested by the Legislative Council Rules Clearinghouse.
- Added definitions of "community-supported agriculture business" and "consumer." Clarified which requirements apply to sale of eggs by community-supported agriculture businesses. Renumbered definitions.
- Clarified that a retail food establishment license is not required for egg producers or egg handlers who sell eggs from a flock that they own directly to consumers at the premises where the eggs were laid or via a community-supported agriculture business.
- Added the term "laying" where needed in the rule to clarify that flock size thresholds apply to the number of laying birds, not total birds, in a flock.
- After receiving additional information from federal officials, DATCP further refined s. ATCP 88.20 (3) regarding acceptable compounds to clean and sanitize eggs, and added s. ATCP 88.20(4) to allow the use of ultraviolet light to sanitize eggs.
- Modified the requirement now in s. ATCP 88.20 (5) (b) previously in s. ATCP 88.20 (4) (6) requiring egg processing wash water to be changed at least every four hours. The modification will allow the use of a continuous water exchange system to ensure that sanitary egg-washing is done. DATCP received one comment stating that draining and re-filling the egg-washing tank, and reheating the new wash water at least every four hours would not be feasible in their business. However, the commenter's business uses a continuous exchange system that meets the same goal.
- Modified s. ATCP 88.08 requiring that eggs be stored a minimum of 6 inches above the floor surface to state that eggs shall be stored in a way to avoid contamination and exposure to

moisture. This requirement is consistent with those in existing rules for Food Processing Plants (ATCP 70) and Food Warehouses (ATCP 71).

In addition, DATCP received the following comments:

- A comment suggesting a licensing fee structure of \$0.011 charged per bird instead of the current fees. The proposal would increase fees for large producers and reduce them for small producers. DATCP did not incorporate this suggestion since license fees were outside the approved scope for the present rule revision.
- A comment suggesting that Wisconsin should expand the federally mandated SE testing program for producers with 3,000 or more laying hens (required under FDA's egg safety rule) to include smaller producers. The commenter noted that eggs from smaller producers can also present a substantial risk of infection. Creating new industry testing requirements is beyond the approved scope of this rulemaking process. However, concerns about public health risks associated with smaller producers are valid. DATCP will evaluate the feasibility of incorporating SE testing of the environment at smaller-scale egg production facilities into the department's standard sampling program.
- A comment requesting an extension of the maximum "use by" date, marked on the egg carton, to longer than 45 days after the eggs were packed. DATCP did not extend this time limit because doing so would create a difference between state and federal requirements which would be confusing for industry and consumers. The same commenter suggested that "use by" date labeling be required, rather than providing a choice between "sell by" and "use by" dates. Implementing this proposed change would also create a confusing difference between state and federal requirements.

Next Steps

If the Board approves this final draft rule, the department will transmit the final draft rule to the Governor for his written approval. After DATCP receives written approval from the Governor, DATCP will submit the rule to the Legislature for review by appropriate legislative committees. If the Legislature has no objections to the rule, the Secretary will sign the final rulemaking order and transmit it for publication.

Appendix A

RULEMAKING HEARING APPEARANCES AND TESTIMONY

Rule Subject:

Eggs

Adm. Code Reference:

ATCP 88

Rules Clearinghouse #:
DATCP Docket #:

CR 14-037

13-R-05

Madison, Wisconsin August 4, 2014

Name/	Testified	Written	Position/Comments
Address/	Y/N	Y/N	
Organization			
Paul Brandt	Y	Y	Favor part and oppose part of the proposal. Indicated that he
1208 Humpty			wanted a change to the licensing fee structure to be based on
Dumpty Road,		-	per-bird basis of 1.1 cent per bird to make it fair.
Reedsville,			- ·
WI 54230			He had questions about the rule's wash water changing
			requirement. Cannot empty and refill wash water tank over
Humpty			lunch hour.
Dumpty Eggs,			
Inc.			Discussed use-by, sell-by, and best-by dates. He felt using a
			use-by date is plain and simple and feels it is the best option.
]			Would like to have proof as to when eggs actually deteriorated
			in quality such that they should not be sold. He believes that if
			eggs are kept cold, they will stay fresh longer than the 45-day
			maximum currently in the rule. Believes the requirement is
			confusing and too open ended.
			He feels the rule goes a long way to ensuring farm safety with
			temperature requirements, but it falls short by not requiring SE
]		testing for flocks of under 3,000. The egg safety program for
			3,000 birds and more is federal, but he felt that it was
			absolutely necessary to have some SE control in flocks of less
			than 3,000 birds. The large salmonellosis outbreak linked to
			eggs produced in Iowa impacted their business negatively, and
			he fears that if an outbreak is linked to a flock of 3,000 or
			fewer birds, it would also impact all businesses. There might
			be fear of the cost of testing for smaller producers. If someone
}			gets sick and if the state doesn't require some form of SE
			testing for smaller producers, then he feels the ill person could
			sue the state. He doesn't want people to have a false sense of

			security about egg safety. There could be a modified system for smaller producers, but there should be some testing system in place.
Ellen Brandt 1208 Humpty Dumpty Road, Reedsville, WI 54230 Humpty Dumpty Eggs, Inc.	Y	Y	Favor part and oppose part of the proposal. Everyone's safety should be valued equally. Someone who purchases eggs at a farmers' market should have their safety protected as much as someone who buys eggs from a large producer. People count on the government to protect public safety for food they purchase. Discussed cost of testing. Currently their farm pays \$40 per SE test, including test analysis and necessary sampling supplies. Felt that if the license fees were restructured, the license savings for small producers would cover the SE testing.

PROPOSED ORDER OF THE WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION ADOPTING RULES

- 1 The Wisconsin department of agriculture, trade and consumer protection hereby proposes the
- 2 following rule to amend ATCP 75 (appendix) (3-202.13); to repeal and recreate ATCP 88; and
- 3 to create ATCP 70.02 (16) (h) and (i), 70.04 (17), 70.06 (11), 70.09 (8), 70.10(6), and ATCP 75
- 4 (appendix) (3-201.11) (H); relating to egg grading, handling and labeling, and affecting small
- 5 business.

Analysis Prepared by the Department of Agriculture, Trade and Consumer Protection

This rule modifies: ATCP 88, Wis. Adm. Code, related to egg grading, handling and labeling; ATCP 70, Wis. Adm. Code, related to food processing plants; and, ATCP 75, Wis. Adm. Code, related to retail food establishments. The rule comprehensively revises ATCP 88 to clarify the regulatory requirements applicable to egg producers and egg handlers. The rule makes minor revisions to ATCP 70 and 75, moving primary egg regulation to ATCP 88 and further defining acceptable sources of eggs to be sold in retail food establishments. By placing requirements for licensing, facilities, equipment and utensils, egg handling operations, packing and labeling, recordkeeping and recall planning in ATCP 88, the rule limits the need for small egg-business operators to consult multiple chapters of rules. The rule implements 2013 Wisconsin Act 245 by eliminating the requirement for small-scale egg producers to hold a food processing plant license when selling eggs to consumers at a farmers' market, on an egg sales route, or at the egg producer's farm. In addition, the rule adopts the existing practice of not requiring a retail food establishment license to be held by egg producers who sell eggs from their flock directly to consumers at their farm or through a community-supported agriculture business. The rule removes obsolete provisions. The rule also provides explanations to improve clarity and spells out federal egg safety registration requirements that must also be met by some egg producers and egg handlers.

Statutes Interpreted

Section 97.29(1)(g) and 2(a), Stats., (Food processing plants) and 97.28, Stats., (Direct sale of eggs).

Statutory Authority

Sections 93.07 (1), 97.09 (4), 97.28 and 97.29 (1) (g) and (2)(a), Stats.

Explanation of Statutory Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to interpret laws under its jurisdiction. DATCP has authority under s. 97.09(4), Stats., to establish and enforce rules that are needed to protect the public from the sale of adulterated or misbranded foods and govern the production, processing, packaging, labeling, transportation, storage, handling, display, sale, and distribution of foods. DATCP has general authority under s. 97.29 (1) (g), Stats., to exempt by rule certain activities from the definition of "food processing." It also has specific authority, pursuant to s. 97.28, Stats., to not require a food processing plant license for collection, packing, and storage of eggs by an egg producer, with a flock of not larger than 150 laying birds, who sells those eggs only to consumers at farmers' markets, on egg sales routes, or at the egg producer's premises.

Related Statutes and Rules

Section 97.28, Stats., requires DATCP to exempt small-scale egg producers who sell eggs directly to consumers on the premises where the eggs are laid, on egg sales routes, and at farmers' markets from the requirement of holding a food processing plant license. Section 97.29 Stats., also authorizes DATCP to exempt certain food processing activities by rule. Section 97.10, Stats., prohibits the sale of adulterated or misbranded food as defined in ss. 97.02 and 97.03, Stats., including food for which the identity is misrepresented. Section 100.183, Stats., prohibits deceptive advertising of food.

Plain Language Analysis

This rulemaking action repeals the existing ATCP 88, Egg Grading, Handling and Labeling, and creates a new rule, ATCP 88, Eggs, to consolidate licensing, egg handling, grading, packing, and retail sale requirements into one rule. Specifically, the proposed rule addresses the following:

Food Processing Plant and Retail Establishment Rules

- The rule revises ATCP 70, Food Processing Plants, to clarify that egg producers, with flocks of not more than 150 laying birds, are exempt from food processing plant licensing requirements, provided they only sell eggs directly to consumers on the premises where the eggs are laid, at a farmers' market, or on an egg-sales route.
- The rule revises ATCP 70, Food Processing Plants, to clarify that egg producers who only collect nest-run eggs to sell to licensed egg handlers, are exempt from food processing plant licensing requirements, provided they register with the department.
- The rule revises ATCP 70, Food Processing Plants, to refer egg handlers who hold a food processing plant license to specific sections of ATCP 88 that relate to construction, maintenance, sanitation, packaging and labeling requirements for egg handling.

• The rule also revises the Wisconsin Food Code found in the appendix of ATCP 75, Retail Food Establishments, to clarify that eggs sold by egg handlers holding a food processing plant license issued by another state, or who are selling eggs directly to the consumer and exempted under s. ATCP 88.02, are allowed to sell eggs at retail. The rule also updates the cited location of restricted egg tolerances from s. ATCP 88.06 to s. ATCP 88.26.

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• The rule retitles ATCP 88 from "Egg Grading, Handling, and Labeling" to "Eggs," reflecting the broader scope of the rule. The revised rule organizes provisions into six subchapters to improve ease of use, reorganizes and renumbers existing provisions that are retained from the current rule, and creates new provisions throughout the rule.

General Provisions

- ATCP 88.01-Definitions. The rule adds definitions to ATCP 88 for "ambient temperature," "balut," "check," "community-supported agriculture business," "consumer," "egg handler," "egg producer," "egg sales route," "farmers' market," "incubator reject," "leaker," "loss," "nest-run," "official egg products plant," "restricted egg," "storage," and "U.S. Consumer Grade B." The rule also expands the definition of "egg," now limited to chicken eggs, to include turkey, duck, goose, guinea or other avian species whose eggs are used for human consumption. The rule also separates each federal regulation related to eggs into a discrete definition. These changes provide additional support and clarity to the rule.
- ATCP 88.02-Licensing and registration. The rule creates a provision describing food processing plant, food warehouse, and retail food establishment licensing and registration requirements for egg producers and egg handlers. The rule continues to require anyone who conducts egg handling activities to acquire a food processing plant license, but specifies two exemptions: 1) Egg producers who collect, pack, and store eggs, from a flock of not more than 150 laying birds, and only sell eggs directly to the consumer at the premises where the eggs are laid, a farmers' market, or on an egg sales route. The rule requires those exempted producers to label packages of eggs, sold under this exemption, as ungraded and uninspected, and include the seller's name, address, and pack date. 2) Egg producers who collect nest-run eggs, register with DATCP, and sell the nest-run eggs to a licensed egg handler. The revision clarifies that a retail food establishment license is required to sell eggs directly to consumers at sites other than the premises where the eggs were laid, including sales at farmers' markets or on egg sales routes. A retail food establishment license is not required for eggs sold directly to consumers at the egg producer's premises or as part of a community-supported agriculture business.
- ATCP 88.04-Federal registrations and records. Under federal law, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) require registration for certain egg producers and handlers, so these agencies may identify those egg producers and handlers required by federal law to meet federal regulations designed to reduce the risk of Salmonella Enteritidis (SE) contamination. ATCP 88 now requires egg producers to register with the FDA if they are required to do so under 21 CFR 118.11 of the federal egg safety rule. Generally, egg producers with flocks of 3,000 laying birds or more

are required to register with the FDA and meet requirements designed to reduce the risk of SE contamination. To ensure Wisconsin egg producers are meeting critical safety requirements in the federal egg safety act, the rule also requires Wisconsin egg handlers, receiving eggs from producers who own 3,000 or more laying birds, to maintain records showing that the producers are registered with the FDA. The rule also requires egg handlers who grade and pack eggs for the ultimate consumer to register with the USDA, if required to do so under 7 CFR 57.690 of the federal egg products inspection act. Egg producers and egg handlers are not required to register if they are exempted under the federal egg safety rule or federal egg products inspection act.

Egg Facilities

- ATCP 88.06-Egg handling and storage facilities. The rule lists requirements, consistent with those for all food processing plants, related to construction and maintenance of egg handling and storage facilities, doors and windows, lighting, toilet facilities, cleaning facilities, garbage and refuse disposal, and control of pests.
- ATCP 88.08-Egg handling rooms. The rule retains the requirement that egg storage areas
 maintain eggs at appropriate temperatures and be equipped with temperature measuring
 devices. The rule also retains the requirement that candling areas be dark enough to permit
 accurate determinations of egg quality. The rule adds cleanliness requirements for egg
 washing and egg grading rooms.
- ATCP 88.10-Operations water. The rule specifies requirements to ensure water, used in egg handling facilities, is tested and meets drinking water standards. Egg handling facilities are required to keep the results of all health-related tests conducted on operations water.

Equipment and Utensils

- ATCP 88.12-Equipment and utensil requirements. The rule presents requirements to ensure
 equipment and utensils used in egg handling establishments are of sanitary design and
 construction.
- ATCP 88.14-Cleaning and sanitizing equipment and utensils. The rule requires that all egg
 contact surfaces of equipment and utensils be cleaned and sanitized after each day's use, or
 more frequently if necessary. It outlines the procedure for obtaining department approval for
 alternative cleaning and sanitizing procedures and methods for storing equipment and
 utensils.

Egg Handling Operations

- ATCP 88.16-Personnel standards. The rule lists requirements for personnel, including cleanliness, clothing and jewelry, employee health, and prohibitions against consumption of food or beverages, or use of tobacco in egg handling rooms.
- ATCP 88.18-Temperature standards. The rule identifies temperature standards for eggs before and after packing and prohibits the sale of shell eggs that have been frozen. The rule maintains those standards and contains added temperature standards for eggs during transport

and at retail sale, with retail sale temperature standards consistent with the Wisconsin Food Code. The rule contains added temperature standards for baluts, which are edible fertile eggs.

- ATCP 88.20-Egg cleaning and storage operations. The rule modifies requirements for egg cleaning and storage. It no longer cites the "List of Proprietary Substances and Nonfood Compounds," which is no longer published by USDA, as a reference for identifying acceptable egg- cleaning or -sanitizing compounds. Instead the rule requires that compounds used to clean or sanitize eggs shall be either 1) generally recognized as safe under 21 CFR parts 182 and 184, and used in accordance with good manufacturing practices under 21 CFR 182.1, 2) approved by the U.S. food and drug administration as a food additive under 21 CFR parts 172 174, and 180, and used in accordance with the conditions of this approval, or 3) approved by the U.S. food and drug administration as a sanitizer under 21 CFR 178.1010, used at concentrations specified therein, and registered for this use with the U.S. environmental protection agency. The rule contains an added provision related to the use of ultraviolet light for sanitizing the surface of shell eggs. The rule requires that dirty eggs, which cannot be cleaned, shall be discarded and that eggs shall be handled and stored in a safe, sanitary and orderly manner to protect the safety of the eggs and allow for ready inspection and movement of eggs.
- ATCP 88.22-Candling. The rule requires use of a candling light or automated grading equipment for determining the interior and exterior quality of eggs, and use of a candling light to verify the performance of automated grading equipment.
- ATCP 88.24-Grading standards for chicken eggs. The rule clarifies that grading standards apply to chicken eggs only. The rule maintains the current requirement that graded eggs sold or distributed in Wisconsin shall be labeled for grade and meet grade B or better standards under the United States grade standards, unless they are clearly labeled as "ungraded." The rule maintains the current size or weight class requirement for chicken egg sizes. The rule adds a table illustrating weights for each size or weight class.
- ATCP 88.26-Minimum tolerance standards. The rule maintains the minimum tolerance standards for selling eggs of grade B quality, whether labeled as "graded" or "ungraded," unless the eggs are sold on the egg producer's premises or as part of a community-supported agriculture business directly to a consumer and the eggs are labeled as "ungraded."
- ATCP 88.28-Restricted eggs. The rule contains an added prohibition against the sale of restricted eggs and provisions describing the disposition of restricted eggs.
- ATCP 88.30-Shell egg protection. The rule maintains the current provision that oiling eggs, to protect shells, shall be performed in a manner that prevents egg contamination and preserves egg quality. The rule removes the requirement that oil used to protect eggs must be listed in the "List of Proprietary Substances and Nonfood Compounds," which USDA no longer publishes, and substitutes a requirement that oil must comply with 21 CFR 172.878 and 178.3620(a) relating to mineral oil.

Packing and Labeling

- ATCP 88.32-Egg packing. The rule maintains current requirements related to egg packing, but revises the title of s. ATCP 82.32(1) to clarify that certain mandatory packing practices are intended to maintain egg quality. The rule contains added provisions that eggs may be packed in used, clean cartons as long as the seller obliterates all carton markings that do not pertain to the eggs being sold.
- ATCP 88.34-Egg labeling. The rule maintains the current requirements related to egg labeling, except that it contains an added requirement that egg cartons include a label with the statement "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly." The rule specifies the font size and location of the safe handling label. The rule maintains requirements related to the packing date, expiration ("sell by") date, and "use by" date and requirements related to egg shipping containers.
- ATCP 88.36-Labeling of baluts. The rule contains an added provision establishing labeling requirements for baluts, including a label clearly indicating that baluts should be stored at a temperature of 41°F or colder.
- ATCP 88.38-Deceptive practices. The rule retains the current provisions against deceptive practices, with an added prohibition against any nutrient content or health claims that do not comply with the requirements of 21 CFR part 101.
- ATCP 88.40-Dealers buying eggs from producers; receipts. The rule maintains the provision related to dealers buying eggs from producers except that, for clarity, it reorganizes the provisions into three, rather than two provisions, and specifies that the producer keeps records of eggs sold to dealers.
- ATCP 88.42-Recall plan. The rule requires egg handlers to develop a written plan for recalling eggs in the event of a foodborne illness linked to the eggs handled at the establishment. The rule identifies the recall plan contents, and requires the egg handler to update the plan as necessary and make it available to the department for inspection and copying upon request.
- ATCP 88.44-Enforcement. The rule includes the regulatory basis for enforcing ATCP 88.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

In general, rules designed to ensure egg safety and consistent quality and marketing of eggs cover activities related to: 1) flock health and farm sanitation, 2) egg grading, sanitation, temperature control, packaging, and labeling at egg processing facilities, and 3) transportation, handling and storage of eggs for retail sale. Federal egg regulations consist of several rules involving two agencies, each responsible for different activities designed to promote the production and sale of safe eggs and consistent egg quality and marketing. The rule clearly differentiates Wisconsin's requirements and those of federal agencies in regulating egg packaging and sales.

Federal Egg Regulations

The Egg Products Inspection Act (Title 21 USC, Chapter 15) authorized the USDA to create regulations (7 CFR Part 57) for egg processing operations. Egg processing operations, now defined in ATCP 88 as "official egg products plants," generally make products other than shell eggs, such as pasteurized whole eggs and dried egg whites. Additional USDA regulations, created under this act, authorize at least yearly inspection of hatcheries and at least quarterly inspection of businesses that pack shell eggs for the ultimate consumer. As part of these inspections, USDA assures that egg packages are labeled "Keep Refrigerated" and packaged eggs are stored at 45°F or colder. For eggs moving in interstate or foreign commerce, federal law and regulations pre-empt state statutes and regulations relating to temperature control, quality or grade, condition, weight or quantity. A voluntary egg grading service is administered by USDA under the authority of the Agricultural Marketing Act of 1946 as amended (Title 7 USC, Chapter 1621 et seq.; referred to in revised ATCP 88 as the "federal egg grading act") and requirements, formerly found in 7 CFR part 56, but now available as guidance from USDA's Agricultural Marketing Service (AMS 56), essentially use the same egg grading standards which are contained in revised ATCP 88.

Under the Federal Food, Drug and Cosmetic Act (Title 21 USC, Chapter 9), and the Public Health Service Act (Title 42 USC, Chapter 264), the US Food and Drug Administration (FDA) has enacted egg safety regulations (21 CFR 16.5 (a) (5) and 21 CFR part 118, now referred to in ATCP 88 as the "federal egg safety rule") applying to shell egg producers with 3,000 or more laying hens at a particular farm, who are not selling all of the eggs directly to consumers or are transporting eggs for processing. The regulations require these egg producers to register with FDA and to develop a written SE prevention plan for each farm. The plan must address procurement of chicks, environmental testing, cleaning and disinfection, biosecurity, pest control, and egg refrigeration. The regulations also require testing of eggs for SE.

Federal and State Regulatory Roles

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for activities related to disease control in flocks of laying hens. In addition, the Agricultural Marketing Service (AMS) is responsible for quality grading for shell eggs and the Shell Egg Surveillance program, which ensures eggs for sale meet Grade B or better standards. Finally, the Food Safety and Inspection Service (FSIS) is responsible for inspecting egg products sold in interstate commerce and re-inspecting imported egg products. The FDA, on the other hand, is responsible for ensuring sanitation and safety control measures at the farm, monitoring safe handling and good manufacturing practices in shell egg packaging plants that do not use the USDA's shell egg grading service, and for managing recalls involving shell eggs or egg products inspected by either the FDA or the USDA.

State and local agencies typically are responsible for working in cooperation with the FDA to inspect shell egg packaging plants that do not use the USDA's shell egg grading service and for inspecting retail food establishments. Wisconsin currently regulates voluntary egg grading in plants that do not use the USDA's shell egg grading service, egg packaging and warehouse activities, and retail sales of eggs.

Comparison with Rules in Adjacent States

Illinois requires egg producers to hold a limited or full license, for \$15 and \$50, respectively. Illinois also assesses a per-case inspection fee on eggs sold in-state. Egg producers are not required to hold an Illinois egg license to sell nest-run eggs from the producer's flock to household consumers for the consumers' own personal use. The eggs must be sold on the premises where the flock is located. Producers who sell eggs to licensed grading stations also do not require an Illinois egg license. A limited Producer-Dealer egg license is required for producers selling graded eggs from their own flock of fewer than 3,000 laying birds when the eggs are sold off the premises where the flock is located. Egg producers who sell eggs from their own flock of 3,000 or more birds or eggs from another person's flock, off the premises where their flock is located, are required to obtain a full Producer-Dealer license. Wholesale and retail sales of eggs must meet all requirements found in the Illinois Egg and Egg Products Act.

Iowa requires handlers of candled and graded eggs to hold a license, the cost of which is based on the number of eggs sold in a "snapshot" month. The fee ranges from \$15 for egg handlers who purchase or handle fewer than 125 cases in the month of April of a calendar year to \$250 for those who purchase or handle 10,000 cases or more during that month. Producers, who sell eggs exclusively from their own flocks directly to handlers, or to consumers, are exempt from licensing.

Michigan does not require a license for selling eggs obtained from flocks of fewer than 3,000 laying hens if the sales are made directly to consumers. Any other sales, including those transacted with consumers by internet, mail, or consignment, are only allowed if the seller holds a \$175 license.

Minnesota assesses an annual inspection fee, based on number of eggs sold, which costs from \$12.50 to \$312. A food handler license is also required for certain sales. The cost of a food handler license is based on the gross annual food sales and ranges from a fee of \$77 for establishments with gross annual food sales of less than \$50,000 to a fee of \$2,001 for establishments with gross food sales of over \$25 million. Producers may sell eggs directly from their farm, to individual customers, without meeting any licensing, registration, or inspection requirements. Producers may also sell eggs at farmers' markets without licensing or registration, but the eggs must be candled, labeled with the producer's name and address and kept at a temperature of 45° F or colder. Producers with fewer than 3,000 hens may sell eggs to grocery stores, restaurants or other food businesses without a license if they register with the Minnesota Department of Agriculture (MDA). There is no fee for registration and no routine inspection of the producer, although MDA may inspect the premises if they receive a complaint about the producer.

Currently, Wisconsin egg handlers must hold a food processing plant license (potentially hazardous foods category) with the license fee based on annual sales and ranging from a fee of \$95 for establishments with annual sales of less than \$25,000 to a fee of \$835 for food processors with annual sales of at least \$250,000. Wisconsin currently also requires egg producers who sell eggs directly to consumers at venues other than their farms or through a community-supported agriculture business, such as at a farmers' market, to hold a retail food establishment license. The fee for a retail food establishment license issued by DATCP ranges from \$45 to \$685,

depending on the scope of the establishment and its total annual sales, with small egg producers typically paying \$45. If the retail sales occur in jurisdictions where local health agents are under contract with the department to conduct retail food establishment inspections, the fees may differ. This ATCP 88 rule now features exemptions from the food processing plant license requirement for producers who sell eggs from small flocks directly to consumers at specified venues, and producers who sell only nest-run eggs to egg handlers. This approach is consistent with that taken in neighboring states to minimize regulatory costs for small-scale direct-sale egg producers.

USDA grading standards are adopted in each of our neighboring states and those standards generally require that eggs sold to retailers must be Grade B or better. Illinois, Iowa, and Minnesota require candled eggs to be stored at 45° F or colder. Michigan requires eggs to be held and transported at no more than 45° F ambient temperature beginning 36 hours after the time of laying. Illinois requires nest-run eggs to be held at 60° F or less at all times. Since temperature control is an essential means of protecting the public from egg-borne illnesses, the Wisconsin rule requires eggs handled by licensed operators to be kept at 45° F or colder before and after packing and during transport, and 41° F or colder for retail sale. Wisconsin egg producers who are exempted under 2013 Wisconsin Act 245 from the requirement to hold a food processing plant license must hold at eggs at 41° F or colder for retail sale.

Illinois, Iowa and Minnesota require record-keeping associated with graded-egg sales and retention of these records for varying lengths of time. Wisconsin's rule is consistent with neighboring states in this regard.

Summary of Factual Data and Analytical Methodologies

In developing this rule, DATCP reviewed rules which governed eggs in other states, reviewed the federal rules related to eggs, and sought input from federal egg regulators and egg industry personnel.

Effect on Small Business

This rule is expected to have a positive impact on small-scale egg producers, as it removes the requirement to obtain a food processing plant license to gather and pack eggs from their flock that are later sold at farmers' markets and on egg sales routes, and removes the requirement to hold a retail food establishment license for sales of eggs to consumers at the egg producer's farm or through a community-supported agriculture business. Egg producers selling nest-run eggs to an egg handler will be required to register with DATCP, which will require a very small expenditure of time and, for some producers, postage, but these producers will not be required to hold a food processing plant license. The rule will not increase licensing fees. Some licensed egg handling operations may need to upgrade facilities, e.g. sinks, walls, temperature monitoring devices, in order to meet requirements in the rule. The rule will have no economic impact on local governmental units or public utility rate-payers.

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1	SECTION 1. ATCP 70.02 (16) (h) and (i) are created to read:
2	ATCP 70.02 (16) (h) The collection, packing and storage of eggs from a flock of not
3	more than 150 laying birds by an egg producer who only sells the eggs directly to consumers at
4	the premises where the eggs were laid, at a farmers' market, or on an egg-sales route.
5	ATCP 70.02 (16) (i) The collection, packaging, and storage of nest-run eggs, as defined
6	in s. ATCP 88.01, from a flock of laying birds by an egg producer who is registered with the
7	department in accordance with s. ATCP 88.02 and who sells the nest-run eggs to an egg handler.
8	SECTION 2. ATCP 70.04 (17) is created to read:
9	ATCP 70.04 (17) EGG HANDLING FACILITIES. Egg handling facilities shall meet the
10	requirements in ss. ATCP 88.06 and ATCP 88.08.
11	SECTION 3. ATCP 70.06 (11) is created to read:
12	ATCP 70.06 (11) EQUIPMENT AND UTENSILS IN EGG HANDLING FACILITIES. Equipment for
13	candling, grading and weighing eggs shall meet the requirements of s. ATCP 88.12 (5).
14	SECTION 4. ATCP 70.09 (8) is created to read:
15	ATCP 70.09 (8) EGG CLEANING AND STORAGE. Cleaning and storage of eggs shall be
16	done in compliance with the requirements of s. ATCP 88.20.
17	SECTION 5. ATCP 70.10 (6) is created to read: